Ryan L. Thompson
WATTS GUERRA LLP
5726 W. Hausman Road, Suite 119
San Antonio, Texas 78249
Office: 210.448.0500
Fax: 210.448.0501
rthompson@wattsguerra.com

Ramon Rossi Lopez, Bar No. 86361
Matthew Ramon Lopez, Bar No. 263134
LOPEZ McHUGH LLP
100 Bayview Circle
Suite 5600, North Tower
Newport Beach, CA 92660
Telephone: (949) 737-1501
Facsimile: (949) 737-1504
rlopez@lopezmchugh.com
mlopez@lopezmchugh.com
Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

EDWARD BACON, INDIVIDUALLY AND AS SUCCESSOR-IN-INTEREST OF THE ESTATE OF FRANCISCA ANDERSON, DECEASED

Plaintiff(s),

v.

MERCK SHARP & DOHME CORP., AMYLIN PHARMACEUTICALS, LLC F/K/A AMYLIN PHARMACEUTICALS, INC., ELI LILLY AND COMPANY, **BIANCA PEREZ** and DOES 1-100

Defendants.

Pertains To Civil Action No.:
3:13-cv-00823

In Re: Incretin-Based Therapies Products Liability Litigation

MDL NO. 2452

FIRST AMENDED COMPLAINT FOR DAMAGES

Case No.:
13md2452 AJB(MDD)

COMES NOW Plaintiff and complains and alleges against Defendants, Does 1 through 100, and each of them as follows:

GENERAL ALLEGATIONS

1. Plaintiff, Edward Bacon, Individually, and as the Successor-in-Interest of the Estate of Francisca Anderson, deceased ("Plaintiff"), by and through his attorneys, Lopez and McHugh LLP and Watts Guerra LLP, brings this action for personal injuries and wrongful death suffered as a proximate result of Francisca Anderson ("Decedent") being prescribed and ingesting the defective and unreasonably dangerous prescription drugs Januvia (sitagliptin phosphate) and Byetta (exenatide synthetic) (collectively, the "Drugs"), prescription medications used to help lower blood sugar levels in adults with diabetes mellitus type 2, which at all times relevant hereto, were manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by Defendants Merck Sharp & Dohme Corp., ("Merck Defendants" for Januvia); Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc., and Eli Lilly and Company (collectively, the "Amylin Lilly Defendants" for Byetta), and Does 1 through 100 (collectively, the "Doe Defendants" for either of Byetta or Januvia) (the Merck Defendants, Amylin Lilly Defendants, and the Doe Defendants collectively are the "Defendants").

2. The true names or capacities whether individual, corporate or otherwise, of the Doe Defendants l through 50, inclusive, are unknown to Plaintiff who therefore, sues said Defendants by such fictitious names. Plaintiff believes and alleges that each of the Defendants designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiff and Decedent as alleged herein.

3. The Doe Defendants 51 through 100 are nominal Defendants, who are heirs or successors under the law who have not yet been identified or who have been identified but have not yet stated their intent be joined as

Plaintiffs in this lawsuit. They are being joined here to ensure that all the heirs are joined and protected and are before this Court. In the event, any of these Defendants elect to participate as Plaintiffs to this lawsuit, the Complaint will be amended accordingly.

4. At all times herein mentioned, each of the Defendants, inclusive of the Doe Defendants, was the agent, servant, partner, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty.

5. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendant, and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

6. The injuries and damages to Plaintiff and Decedent were caused by the wrongful acts, omissions, and fraudulent representations of Defendants, many of which occurred within the State of California.

7. At all times herein mentioned, Defendants were each engaged in the business of, or were successors in interest to, entities engaged in the business of research, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or

selling the Drugs.

8. At all times herein mentioned Defendants were each authorized to do or otherwise engaged in business within the State of California and did in fact supply the aforementioned products within the State of California and elsewhere.

9. At all times herein mentioned, the officers and directors of Defendants authorized and directed the production and promotion of the Drug when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the Drug, and thereby actively participated in the tortious conduct which resulted in the physical injuries described herein.

JURISDICTION AND VENUE

10. Jurisdiction is proper in this court pursuant to 28 USC §1332 for the reason that there is complete diversity of citizenship between Plaintiff and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

11. This Court has jurisdiction over the non-resident Defendants because they have done business in the State of California, have committed a tort in whole or in part in the State of California, and have continuing contacts with the State of California.

12. In addition, venue of this case is proper in the Southern District of California pursuant to 28 U.S.C. § 1391(b)(1) because all Defendants are residents of this state.

13. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Southern District of California.

14. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

15. Finally, venue of this case is proper in the Southern District of California pursuant to the Court's direct filing order entered in this MDL.

PLAINTIFF

16. Plaintiff Edward Bacon is a natural person currently residing in Billings, Montana. Plaintiff is the surviving spouse and Successor-in-Interest of Francisca Anderson, deceased (the "Decedent"), who was also a resident of Billings, Montana at the time Decedent ingested the Drug, was diagnosed with pancreatic cancer, and ultimately died of said cancer. As Plaintiff herein, Edward Bacon is bringing Plaintiff's individual claims, including Plaintiff's claim for the wrongful death of the Decedent, and the claims of the estate.

17. Decedent was prescribed and used the Drugs beginning in or around February 17, 2006, and continued said use through at least June 2012. On or about December 6, 2012, Decedent suffered severe physical, economic and emotional injuries as a result of said Drugs, including but not limited to Decedent's being diagnosed with pancreatic cancer. Plaintiff and Decedent were unaware that Decedent's injuries were caused by the Drugs until shortly before the filing of this complaint.

NOMINAL DEFENDANTS

18. Bianca Perez is a nominal defendant residing in Panoma, CA, John Doe 51 and John Doe 52 are nominal defendants residing in Mexico and John Doe 53 and John Doe 54 are nominal defendants whom whereabouts are unknown at this time.

DEFENDANTS

19. Merck Sharp & Dohme Corp. ("MSDC") is a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Rd., Kenilworth, NJ 07033. Merck may be served at CT Corporation System, 818 W. Seventh St., Los Angeles, CA 90017. MSDC has conducted business

and derived substantial revenue from within the State of California.

20. Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc. ("Amylin, LLC") is a Delaware limited liability company, which has its principal place of business is at 9360 Towne Centre Drive, Suite 100, San Diego, CA 92121-3030. Amylin, LLC may be served at it's physical address: 9360 Towne Centre Drive, Suite 100, San Diego, CA 92121-3030, or by and through its registered agent: CT Corporation System, 818 W. Seventh St., Los Angeles, CA 90017.

21. Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly may be served by and through its registered agent: National Registered Agents, Inc., 2875 Michelle Dr., Ste. 100, Irvine, CA 92606.

FACTUAL ALLEGATIONS

22. This is an action for injuries and damages suffered by Plaintiff and Decedent as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Drugs.

23. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold the Drugs as prescriptions that, along with diet and exercise, are designed to help lower blood sugar levels in adults with type 2 diabetes.

24. According to the American Diabetes Association, "Type 2 diabetes is the most common form of diabetes. Millions of Americans have been diagnosed with type 2 diabetes. […] In type 2 diabetes, either the body does not produce enough insulin or the cells ignore the insulin. Insulin is

necessary for the body to be able to use glucose for energy. When you eat food, the body breaks down all of the sugars and starches into glucose, which is the basic fuel for the cells in the body. Insulin takes the sugar from the blood into the cells. When glucose builds up in the blood instead of going into cells, it can lead to diabetes complications."1

25. Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels or 'hyperglycemia', which is the hallmark of the condition.

26. Diabetes remains the most frequent cause of blindness, amputations and dialysis worldwide.[2] With the current estimate of more than 350 million patients worldwide[3] it is considered to be one of the major health challenges of the 21st century.

27. Januvia and Byetta are supposed to help prevent these diabetic complications.

28. The two most recently approved classes of therapeutic agents for the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1) receptor (GLP-1R) agonists (such as Byetta) and dipeptidyl peptidase-4 (DPP-4) inhibitors (such as Januvia), exert their actions through potentiation of incretin receptor signaling. Incretins are gut-derived hormones, principally GLP-1 and glucose-dependent insulinotropic peptide (GIP), that are secreted at low basal levels in the fasting state.

29. Januvia was approved by the Food and Drug Administration ("FDA") on or about October 16, 2006 "as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus as

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1 http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2

2 ID

3 IDF Diabetes atlas, http://www.idf.org/diabetesatlas/5e/diabetes.

monotherapy and in combination with metformin or a PPAR□ agonist (e.g., thiazolidinediones) when diet and exercise plus the single agent do not provide adequate glycemic control."4

30. Following FDA approval, Januvia was launched by Defendants in North America in 2006.

31. Januvia is the first in a new class of Drug that inhibit the proteolytic activity of dipeptidyl peptidase-4 (DPP-4), thereby potentiating the action of endogenous glucoregulatory peptides, known as incretins.[5]

32. Byetta was approved by the FDA in April of 2005 and was marketed to the medical community and general public shortly thereafter.

33. Byetta is a member of the new class of drugs known as glucagon-like peptide-1 (GLP-1) receptor agonists.

34. In February 2010, concerns were published regarding the GLP-1 drugs, including Byetta, and the DPP-4 inhibitors, including Januvia, and their potential linkage with pancreatic cancer.

35. Writing in DIABETES CARE, Butler *et al*. published *GLP-1–Based Therapy for Diabetes: What You Do Not Know Can Hurt You*'[6] wherein they wrote, "History has taught us that enthusiasm for new classes of Drug, heavily promoted by the pharmaceutical companies that market them, can obscure the caution that should be exercised when the long-term consequences are unknown. Of perhaps greatest concern in the case of the GLP-1–based Drug, including GLP-1 agonists and dipeptidyl peptidase-4 (DPP-4) inhibitors, is preliminary evidence to suggest the potential risks of

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4http://www.accessdata.fda.gov/Drugatfda_docs/appletter/2006/021995s000ltr

5 Drucker D, Easley Continuing, Kirkpatrick P. Sitagliptin. Nature Reviews Drug Discovery. Feb. 2007. 6:109-10.

6 Butler PC, Dry D, Elashoff D. GLP-1–Based Therapy for Diabetes: What You Do Not Know Can Hurt You Diabetes Care February 2010 33:453-455.

asymptomatic chronic pancreatitis and, with time, pancreatic cancer."

36. In addition, these researchers wrote, "However, in the context of a new class of medical therapy, the proverb 'What you do not know cannot hurt you' clearly does not apply. We feel that enough preliminary evidence has accumulated to suggest that there is a plausible risk that long-term recipients of GLP-1–based therapy may develop asymptomatic chronic pancreatitis (Fig. 1), and worse, subsequently a minority of individuals treated by this class of Drug may develop pancreatic cancer."

37. In February 2011, the journal Gastroenterology published on-line the work of Elashoff *et al.*[7] titled, *Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies*.

38. These researchers used the FDA Adverse Event Reporting System (AERS) with the primary goal of their analysis being to assess the association between treatment with Byetta or Januvia and an adverse event report of pancreatitis, where the drugs were listed as the primary suspect associated with a pancreatitis report in the database. A secondary goal was to examine the FDA AERS database for reported pancreatic or thyroid cancer associated with use of Byetta or Januvia, with various other anti-diabetic drugs used as controls. Metformin was not used as a control drug because it has been reported to decrease the risk of pancreatic cancer.

39. These researchers reported that pancreatitis, inflammation of the pancreas, was >10-fold more frequently reported as an adverse event for patients administered Byetta and >6-fold more frequently reported in patients prescribed Januvia. Both these associations were statistically significant.

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7 Elashoff M, Matveyenko AV, Gier B, Elashoff R & Butler PC Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies. Gastroenterology (2011) 141:150-156.

40. Because pancreatitis is a known risk factor for pancreatic cancer,8 Elashoff *et al.* evaluated the reported rates of pancreatic cancer with with Byetta and Januvia compared to control events relative to Avandia (rosiglitazone).

41. The reported event rate for pancreatic cancer was 2.9-fold greater in patients treated with Byetta compared to other therapies. The reported event rate for pancreatic cancer was 2.7-fold greater with Januvia (and other DPP-4 inhibitors) than other therapies.

42. Because pancreatitis acts as a risk factor for subsequent pancreatic cancer through the mechanisms of chronic inflammation and increased cell turnover,9 it is not unforeseen that there is a progressive increased risk of pancreatic cancer with prolonged exposure to the Drugs.

43. These researchers noted that the potential to increase the risk of cancer might be expected to occur by "permitting declaration of tumors previously held in check by an intact immune system" as has been published by others within the world's medical literature.

44. On May 13, 2011, the Arzneimittelkommission der deutschen Ärzteschaft (Drug Commission of the German Medical Association - AkdÄ) published *Pancreatic cancers associated with exenatide (Byetta ®)* on its website.[10]

45. In the German adverse event database, reporting of pancreatic cancer was also unusually high in association with Byetta (11 cases in 4

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8 Rebours V, Boutron-Ruault MC, Schnee M, et al. The natural history of hereditary pancreatitis: a national series. Gut 2009;58: 97–103.

9 Bhanot UK, Moller P. Mechanisms of parenchymal injury and signaling pathways in ectatic ducts of chronic pancreatitis: implications for pancreatic carcinogenesis. Lab Invest 2009;89:489– 497.

10http://www.akdae.de/Arzneimittelsicherheit/Bekanntgaben/Archiv/2011/20110513

years, with yearly 15,000-25,000 treated patients).[11]

46. The period between the start of treatment with Byetta and a diagnosis of pancreatic cancer was on average 12.2 months (within a range of 2-33 months).

47. Some of the manufacturers of the Drugs have suggested that the most likely reason for the apparent association between the use of these Drugs and acute pancreatitis is the increased risk of pancreatitis in patients with type 2 diabetes.12

48. However, animal studies showing pancreatitis as a consequence of GLP-1 mimetic therapy (and other incretin-based therapies) challenge that assumption and lead to the conclusion that asymptomatic chronic pancreatitis is an adverse effect of GLP-1-based treatment, which is further confirmed by specific studies as applied to sitagliptin13 and Exenatide (Byetta).14

49. GLP-1 receptors are abundantly expressed in the pancreas, and Januvia therapy has been shown to lead to increased pancreatic ductal replication, acinar to ductal metaplasia or cellular change, and, less

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11 Arzneimittelkommission der deutschen Ärzteschaft. Aus der UAW-Datenbank": Pankreaskarzinome im Zusammenhang mit Exenatid (Byetta®). Dtsch Arztebl, (2011) 108: A-1080; (as cited by Vangoitsenhoven R, Mathieu C, Van Der Schueren B. GLP1 and cancer: friend or foe? Endocrine Related Cancer. 2012 Jun 12. [Epub ahead of print])

12 Monami M, Lamanna C, Marchionni N, Mannucci E. Rosiglitazone and risk of cancer: a meta-analysis of randomized clinical trials. Diabetes Care 2008;31:1455–1460.

13 Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes, interactions with metformin. Diabetes 2009;58: 1604–1615.

14 Nachnani JS, Bulchandani DG, Nookala A, et al. Biochemical and histological effects of exendin-4 (exenatide) on the rat pancreas. Diabetologia 2009;58:1604–1615.

commonly, acute pancreatitis in a rat model of type 2 diabetes.[15]

50. Increased ductal turnover and acinar to ductal metaplasia are both well-established characteristics of chronic pancreatitis in humans.16

51. It has also been suggested that immunomodulatory effects of DPP-4 inhibition might increase risk for all cancers.17,18

52. Butler *et al*.19 also reported that human and rodent pancreases contain numerous GLP-1 receptors in areas in which cancer is thought to originate, and mice that are genetically predisposed to pancreatic cancer develop the disease more quickly than usual in response to Byetta.

53. In April 2012, Public Citizen, a non-profit consumer-advocacy organization based in Washington DC, sent a petition to the FDA to withdraw another drug in the GLP-1 class, Victoza (liraglutide) from the market.

54. Dr. Sidney Wolfe, director of the health and research group at Public Citizen, said at that time, "We don't just go after Drug casually…(W)e only go after Drug when there is clear evidence of unique dangers or risks, and when there is no evidence of a unique clinical advantage."

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15 Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes, interactions with metformin. Diabetes 2009;58: 1604–1615.

16 Bhanot UK, Moller P. Mechanisms of parenchymal injury and signaling pathways in ectatic ducts of chronic pancreatitis: implications for pancreatic carcinogenesis. Lab Invest 2009;89:489– 497.

17 Havre PA, Abe M, Urasaki Y, et al. The role of CD26/dipeptidyl peptidase IV in cancer. Front Biosci 2008;13:1634–1645.

18 Matteucci E, Giampietro O. Dipeptidyl peptidase-4 (CD26): knowing the function before inhibiting the enzyme. Curr Med Chem 2009;16:2943–2951.

19 Gier B, Matveyenko AV, Kirakossian D, et al. Chronic GLP-1 Receptor Activation by Exendin-4 Induces Expansion of Pancreatic Duct Glands in Rats and Accelerates Formation of Dysplastic Lesions and Chronic Pancreatitis in the KrasG12D Mouse Model. Diabetes May 2012 vol. 61 no. 5 1250-1262

55. Dr. Wolfe said at the time that his concern extends to other diabetes drugs that alter the GLP-1 pathway, which would include Januvia and Byetta.

56. In February 2013, the results of the first case-controlled epidemiological study looking at the Drugs and their effects upon the pancreas were published by Singh et. al. out of the Johns Hopkins School of Medicine and School of Public Health.[20]

57. Singh et al used administrative claims data from the BlueCross Blue Shield Association plans of Tennessee, Hawaii, Michigan, and North Carolina; Highmark, Inc. and Independence Blue Cross of Pennsylvania; and Wellmark, Inc. of Iowa and South Dakota. They evaluated 1,269 hospitalized cases with acute pancreatitis using a validated algorithm and 1,269 control subjects matched for age category, sex, enrollment pattern, and diabetes complications. The strengths of this study include the large size of the sample, the ability to adjust for confounders, and the independence of the authors from the companies marketing the Drugs.

58. After adjusting for available confounders and metformin hydrochloride use, current use of GLP-1–based therapies within 30 days demonstrated the existence of a statistically significant adjusted Odds Ratio (OR) of 2.24 in relation to the development of acute pancreatitis. For those patients who had used the GLP-1-based therapies in the recent past 30 days, and less than 2 years, the statistically significant OR was 2.01 for the development of acute pancreatitis as compared to the odds of 'nonusers' of these drugs. 'Any use' was also associated with statistically significantly higher odds of acute pancreatitis with a statistically significant adjusted OR

20 Singh S et al. Glucagonlike Peptide 1–Based Therapies and Risk of Hospitalization for Acute Pancreatitis in Type 2 Diabetes Mellitus. JAMA Intern Med. 2013 Feb 25:1-6. [Epub ahead of print].

of 2.07. Significantly, the Confidence Intervals for each of these findings were "tight" attesting to the robust nature of their findings.

59. The results from the case-controlled epidemiological study "...support findings from the previously mechanistic studies and spontaneous reports submitted to the US Food and Drug Association that such an association may be causal."[21] The import of this language - "...*such an association may be causal"* - by these epidemiologists and physicians as peer-reviewed and published in the *Journal of the American Medical Association - Internal Medicine*, one of the finest medical journals in the world, cannot be understated.

60. It is easy to appreciate the increased risk of pancreatitis associated with the Drugs is of critical importance. Antecedent pancreatitis is the most common risk factor for subsequent pancreatic cancer. Analysis of the FDA adverse event reporting system, discussed *supra,* already showed a signal for pancreatic cancer with exenatide and sitagliptin by 2009, and likely, much earlier.

61. Pancreatic cancer develops after progressive accumulation of somatic mutations leads to the formation of pancreatic intraepithelial neoplasia (PanIN) of increasing grade that, in a subset of individuals, transforms to malignant neoplasms.[22]

62. The PanIN lesions are relatively common in middle-aged adults and express the GLP-1 receptor. Glucagon-like peptide 1 induces growth of lesions similar to intraductal papillary mucinous neoplasia in rats and

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21 *Id.*

22 Gier B, Butler PC. Glucagonlike Peptide 1-Based Drugs and Pancreatitis: Clarity at Last, but What About Pancreatic Cancer?: Comment on "Glucagonlike Peptide 1-Based Therapies and Risk of Hospitalization for Acute Pancreatitis in Type 2 Diabetes Mellitus". JAMA Intern Med. 2013 Mar 5:1-3. doi: 10.1001/jamainternmed.2013.3374. [Epub ahead of print]

accelerates dysplasia of PanIN lesions and pancreatitis in mice prone to pancreatic cancer.[23]

63. Therefore, in those individuals with preexisting PanIN lesions or intraductal papillary mucinous neoplasia, GLP-1–based therapy promotes growth of these lesions, causing partial ductal obstruction and pancreatitis in some individuals. Of even greater concern, GLP-1–based therapy can accelerate the progression and transformation of premalignant PanIN lesions, much like the effect of estrogen therapy in women with estrogen receptor–expressing breast neoplasia. In other words, the incretin-based therapies are to pancreatic premalignant cells as wheat is to the prairie fire.

64. On March 22 2013, in an on-line publication within the journal *Diabetes,* Butler et al published the results of their examinations of the pancreata obtained from age-matched brain dead organ donors with and without diabetes treated by incretin-based therapies (> 1 yr) or other therapy and non diabetic controls.[24]

65. These researchers observed that pancreatic mass was increased approximately 40 percent in diabetes patients treated with incretin-based therapies compared to that in individuals with diabetes not treated with such agents, and that the increase was statistically significant. They also observed that the pancreatic fractional insulin area, that area occupied by

23 Gier B, Matveyenko AV, Kirakossian D, Dawson D, Dry SM, Butler PC. Chronic GLP-1 receptor activation by exendin-4 induces expansion of pancreatic duct glands in rats and accelerates formation of dysplastic lesions and chronic pancreatitis in the KrasG12D mouse model. *Diabetes*. 2012;61(5): 1250-1262.

24 Butler AE, Campbell-Thompson M, Gurlo T, Dawson DW, Atkinson M, Butler PC. Marked Expansion of Exocrine and Endocrine Pancreas with Incretin Therapy in Humans with increased Exocrine Pancreas Dysplasia and the potential for Glucagon-producing Neuroendocrine Tumors. Diabetes. 2013 Mar 22. [Epub ahead of print]

each cell type, was approximately 60 percent reduced in diabetics patients not treated with incretin-based therapies compared to non-diabetic controls, again, a statistically significant result. In contrast, they observed that the pancreatic fractional insulin area was approximately 5-fold increased in diabetic patients treated with incretin-based therapies when compared to individuals not treated with incretin-based therapies, also statistically significant.

66. Furthermore, actual beta (ß) cell mass was increased 6-fold in incretin-based therapies treated diabetics and the ß cell mass was 3-fold greater in individuals with diabetes treated with incretin-based therapies in comparison to non diabetic controls, both observations also being statistically significant. These researchers noted that the increased pancreatic mass in diabetics induced by incretin-based therapies was accompanied by increased whole pancreas cell and an increase in the presence of pancreatic intraepithelial neoplasia (PanINs), both observations being statistically significant.

67. The observation by Butler et al that the pancreatic mass of the individuals with diabetes treated with incretin-based therapies was increased by 40 percent in comparison to diabetics not treated with incretin-based therapies is consistent with the prior rodent studies that revealed proliferative actions of GLP-1 on the exocrine pancreas – extending the animal studies to human studies.[25, 26]

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25 Matveyenko AV, Dry S, Cox HI, Moshtaghian A, Gurlo T, Galasso R, Butler AE, Butler PC: Beneficial endocrine but adverse exocrine effects of sitagliptin in the human islet amyloid polypeptide transgenic rat model of type 2 diabetes: interactions with metformin. Diabetes 2009;58:1604-1615

26 Gier B, Matveyenko AV, Kirakossian D, Dawson D, Dry SM, Butler PC: Chronic GLP-1 receptor activation by exendin-4 induces expansion of pancreatic duct glands in rats and accelerates formation of dysplastic lesions and chronic pancreatitis in the Kras(G12D) mouse model. Diabetes

Footnote continued on next page

68. Of further concern is the marked alpha (□) cell hyperplasia, glucagon expressing microadenomas and glucagon expressing neuroendocrine tumors noted by Butler et al in individuals with diabetes treated with incretin-based therapies. These findings reproduce the □ cell hyperplasia, abnormal □ cell distribution, and predisposition to glucagon expressing neuroendocrine tumors previously reported in the literature.[27, 28, 29]

69. As a result of the defective nature of Januvia and Byetta persons who were prescribed and ingested Januvia and Byetta for even a brief period of time, including Decedent herein, were at increased risk for developing life-threatening pancreatic cancer. Once that cancer spreads, a patient stands just a 1.8% chance of surviving for longer than five years.

70. "At present, the GLP-1 class of drugs is heavily promoted (and prescribed) as having purported advantages that outweigh its risks."[30] Singh et al, *supra,* show that, "…despite large numbers of underpowered studies claiming the contrary from marketing companies, little is yet known

Footnote continued from previous page
2012;61:1250-1262

27 Gelling RW, Du XQ, Dichmann DS, Romer J, Huang H, Cui L, Obici S, Tang B, Holst JJ, Fledelius C, Johansen PB, Rossetti L, Jelicks LA, Serup P, Nishimura E, Charron MJ: Lower blood glucose, hyperglucagonemia, and pancreatic alpha cell hyperplasia in glucagon receptor knockout mice. Proc Natl Acad Sci U S A 2003;100:1438-1443

28 Yu R, Dhall D, Nissen NN, Zhou C, Ren SG: Pancreatic neuroendocrine tumors in glucagon receptor-deficient mice. PLoS One 2011;6:e23397

29 Zhou C, Dhall D, Nissen NN, Chen CR, Yu R: Homozygous P86S mutation of the human glucagon receptor is associated with hyperglucagonemia, alpha cell hyperplasia, and islet cell tumor. Pancreas 2009;38:941-946

30 Gier B, Matveyenko AV, Kirakossian D, Dawson D, Dry SM, Butler PC. Chronic GLP-1 receptor activation by exendin-4 induces expansion of pancreatic duct glands in rats and accelerates formation of dysplastic lesions and chronic pancreatitis in the KrasG12D mouse model. *Diabetes*. 2012;61(5): 1250-1262.

about long-term adverse effects of the GLP-1 class of drugs on the exocrine pancreas."[31] A striking finding in the studies by Butler et al[32] is the marked expansion of the exocrine and endocrine compartments of the pancreas with incretin-based therapies. The findings of an increased pancreatic mass, increased PanIN lesions, and endocrine proliferations by Butler et al in response to GLP-1 mimetic therapy adds significantly to concerns already shown regarding the adverse actions of GLP-1 mimetic therapy to induce pancreatitis and accelerate pancreatic dysplasia.[33] Prior reports concerning pancreas changes with incretin-based therapy were generally confined to studies of rodent pancreas, but have since been unquestionably extended by Butler et al to humans with the added concern of developing neuroendocrine tumors. These findings demonstrate the effects of long term GLP-1 related therapy with respect to both unintended proliferative actions on the exocrine pancreas and an increased risk of neuroendocrine tumors.

71. Due to the flawed formulation of the Drugs, ingestion of any of the Drugs increases the risk of pancreatic cancer in those diabetic patients to whom it is prescribed.

72. Defendants concealed their knowledge that Byetta and Januvia, can cause life threatening pancreatic cancer from Decedent, other consumers, the general public, and the medical community. Indeed, the manufacturers of Byetta and Januvia do not even mention 'pancreatic

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31 ID

32 Butler AE, Campbell-Thompson M, Gurlo T, Dawson DW, Atkinson M, Butler PC. Marked Expansion of Exocrine and Endocrine Pancreas with Incretin Therapy in Humans with increased Exocrine Pancreas Dysplasia and the potential for Glucagon-producing Neuroendocrine Tumors. Diabetes. 2013 Mar 22. [Epub ahead of print]

33 Elashoff M, Matveyenko AV, Gier B, Elashoff R, Butler PC: Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies. Gastroenterology 2011;141:150-156

cancer' in their drugs' respective product inserts.

73. Specifically, the Defendants did not adequately inform consumers and the prescribing medical community about the risks of pancreatic cancer associated with Byetta and Januvia usage, nor did Defendants warn or otherwise advise physicians to institute monitoring procedures looking for the first signs of changes within the pancreas.

74. The current warnings for the Drugs are simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff and Decedent herein.

75. Even if the warnings were sufficient, which Plaintiff strongly denies, Byetta and Januvia still lack any benefit sufficient to tolerate the extreme risk posed by the ingestion of these drugs. Other drugs to treat diabetes are available. Byetta and Januvia are quite simply too dangerous and defective as formulated. The Defendants should withdraw Byetta and Januvia from the market.

76. Defendants willfully, wantonly, and with malice withheld the knowledge of increased risk of pancreatic cancer in users of Byetta and Januvia to prevent any chances of their product's registration being delayed or rejected by FDA.

77. As the manufacturers and distributors of Byetta and Januvia, Defendants knew or should have known that the Drugs' usage was associated with pancreatic cancer.

78. With the knowledge of the true relationship between use of Byetta and Januvia and pancreatic cancer, rather than taking steps to pull the drugs off the market or provide strong warnings, Defendants promoted and continue to promote Byetta and Januvia as a safe and effective treatment for adults with type 2 diabetes.

79. Byetta and Januvia are some of the top selling drugs in the

country.

80. In 2010, the worldwide sales of Byetta reached $0.710 billion and visiongain predicts sales to reach $1.00 billion by 2015 and $1.28 billion by 2021. 34

81. Januvia is one of the top selling drugs in the country, and further, Januvia is one of Merck's best sellers with $919 million in sales the first quarter of 2012 alone.[35]

82. While Defendants have enjoyed great financial success from their blockbuster drugs, they continue to place American citizens at risk of developing deadly pancreatic cancer.

83. Consumers, including Decedent, who have used Byetta and Januvia for treatment of their type 2 diabetes had several alternative safer products available to treat their condition and have not been adequately warned about the significant risks and lack of benefits associated with Byetta and Januvia therapy.

84. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and Decedent's physicians the true and significant risks associated with Byetta and Januvia use.

85. As a result of Defendants' actions, Decedent and Decedent's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Decedent would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Decedent's Byetta and Januvia use were the direct and proximate result of Defendants' conduct.

86. At all times relevant hereto, the Defendants have directly marketed and distributed the Drugs to the medical community.

34 www.pipelinereview.com/store/toc/sample_pages_vg0151.pdf

35 Merck 2012 Januvia Product Insert

87. At all times relevant hereto, the Defendants have directly marketed the Drugs to the consuming public throughout the United States, including the Decedent, herein.

88. Defendants departed from and failed to meet requirements of laws, regulations and class and product specific requirements including failing to undertake adequate post approval marketing studies on safety of the Drugs as dictated by good pharmaceutical science standards.

89. Defendants both over-promoted the Drugs and under-warned about their risks, including:

a. in print advertising;

b. on their websites and blogs;

c. advertised to users that use of the Drugs was "safe" whereas it was not and Defendants knew or should have know it was not; and

d. promoted the Drugs to doctors, clinics and users as safer than (or as safe as) other diabetes drugs.

90. Defendants did not perform adequate safety testing on the Drugs as required by good pharmaceutical science practice.

91. Defendants failed to provide proper and full information as to the safety of the Drugs.

92. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied the Drugs to the purchaser.

93. Defendants have never sought to enlarge their warnings to include a warning about pancreatic cancer risks associated with the use of the Drugs.

94. Instead, Defendants marketed (and continue to market) the Drugs as having a low risk of side effects and continue to minimize the

Drugs' deadly side effects.

95. Manufacturers such as the Defendants, herein, are required to have systems in place to collect and analyze any complaints they receive from doctors and hospitals about their products.

96. Defendants did not timely apprise the F.D.A., the public, nor treating physicians of the defect(s) in Defendants' Drugs, despite Defendants' knowledge that injuries had occurred and had been reported to Defendants due to the above-described defects.

97. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that the Drugs were of such a nature that they were not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

98. Decedent and Decedent's prescribing health care providers were unaware of the true degree and incidence of pancreatic cancer associated with the use of the Drugs and would have used and prescribed other methods for diabetes control if they had been so informed.

99. Decedent suffered from severe and personal injuries, which were permanent and lasting in nature, including death, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications.

100. As a direct and proximate result of the aforesaid conduct of Defendants and each of them as set forth hereinafter, Decedent suffered injuries, including but not limited to pancreatic cancer, which resulted in her death and damages to Decedent and Plaintiff in a sum in excess of the jurisdictional limits of the Court.

101. As a direct and proximate result of the aforesaid conduct of the Defendants, and each of them, Decedent was compelled to incur obligations for physicians, surgeons, nurses, hospital care, medicine, hospices, x-rays, medical supplies, and other medical treatment, the true and exact amount thereof being unknown to Plaintiff at this time, and Plaintiff prays leave to amend this complaint accordingly when the true and exact cost thereof is ascertained.

102. As a further direct and proximate result of the said conduct of the Defendants, and each of them, Decedent suffered a loss of income, wages, profits and commissions, a diminishment of earning potential, and other pecuniary losses, the full nature and extent of which are not yet known to Plaintiff; and leave is requested to amend this complaint to conform to proof at the time of trial.

103. By reasons of the premises, Plaintiff and Decedent have been caused great pain and suffering.

STATEMENT OF DECEDENT'S INJURIES

104. On or about February 17, 2006, Decedent was prescribed and began taking Byetta upon the direction of Decedent's physician for long-term maintenance of Type II diabetes, and Decedent continued to take Byetta until on or about November 15, 2011. On or about May 11, 2012, she was prescribed to begin taking Januvia upon the direction of Decedent's physician for long-term maintenance of Type II diabetes, and Decedent continued to take Januvia until at least June 2012.

105. As a direct result of the ingestion of Januvia and Byetta the Decedent was diagnosed with pancreatic cancer in or about December 6, 2012. Had Decedent and/or Decedent's physician been properly warned by Defendants regarding the risk of pancreatic cancer from usage of these prescription medications, Decedent's physician would have not prescribed

the Drugs and Decedent would never had ingested these prescription medications.

106. As a direct result of being prescribed the Drugs for this period of time, Decedent was permanently and severely injured, having suffered serious consequences from Decedent's usage of the Drugs, including but not limited to, the development of pancreatic cancer, which led to her untimely death on April 26, 2013.

107. Decedent, as a direct and proximate result of her Januvia and Byetta use, suffered severe mental and physical pain and suffering prior to her death, along with economic loss.

108. As a proximate result of Defendants' acts and omissions, Decedent suffered the injuries described hereinabove due to her ingestion of the Drugs. Plaintiff accordingly seeks damages associated with these injuries.

109. Decedent would not have used the Drugs had Defendants properly disclosed the risks associated with their use.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

110. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

111. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and are now, engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Januvia and Byetta at issue in this lawsuit. The Januvia and Byetta manufactured by Defendants reached Decedent without substantial changes and were ingested as directed. The

Drugs were defective and unreasonably dangerous when they entered into the stream of commerce and when used by Decedent.

112. The Decedent was administered the Drugs for their intended purposes.

113. The Decedent could not have discovered any defect in the Drugs through the exercise of care.

114. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Januvia and Byetta were incomplete and inadequate.

115. Decedent did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Decedent or to Decedent's treating physicians. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous or incomplete.

116. Defendants had a continuing duty to provide consumers, including Decedent, and Decedent's physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with the Drugs, as it became or could have become available to Defendants.

117. Defendants marketed, promoted, distributed and sold unreasonably dangerous and defective prescription drugs, Januvia and Byetta, to health care providers empowered to prescribe and dispense the Drugs to consumers, including Decedent, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community

about the risk and benefit balance of the Drugs, which resulted in injury to Decedent and ultimately the death of Decedent.

118. Despite the fact that Defendants knew or should have known that the Drugs caused unreasonable and dangerous side effects, they continued to promote and market the Drugs without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

119. Defendants knew or should have known that consumers, Decedent specifically, would foreseeably and needlessly suffer injury or death as a result of Defendants' failures.

120. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Decedent and to Decedent's intermediary physicians, in at least the following ways:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Decedent and Decedent's physicians to the dangerous risks of the Drugs including, among other things, their tendency to increase the risk of, and/or cause, the development of pancreatic cancer;

b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, pancreatic cancer; and

c. Defendants continued to aggressively promote and sell the Drugs even after they knew or should have known of the unreasonable risks of developing pancreatic cancer from ingestion of the Drugs.

121. Defendants had an obligation to provide Decedent and

Decedent's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to the Drugs, and/or that there existed safer and more or equally effective alternative drug products.

122. By failing to provide Decedent and Decedent's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to the Drugs, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

123. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Decedent and the public.

124. Defendants' actions described above violated the federal and state Food, Drug and Cosmetic Acts and rendered the Drugs misbranded.

125. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to the Drugs and suffered the injuries and damages set forth hereinabove.

COUNT II

STRICT PRODUCTS LIABILITY - DESIGN DEFECT

126. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

127. Defendants are the manufacturers, designers, distributers, sellers and suppliers of the Drugs, who sold the Drugs in the course of business.

128. The Drugs manufactured, designed, sold, marketed, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

129. The Drugs administered to Plaintiff was defective in design or formulation in the following respects:

a. When it left the hands of the Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;

b. Any benefit of these Drugs were outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;

c. The dosages and/or formulation of the Drugs sold by the Defendants was unreasonably dangerous;

d. There are no patients for whom the benefits of the Drugs outweighed the risks;

e. The subject product was not made in accordance with the Defendants' specifications or performance standards;

f. There are no patients for whom the Drugs is a safer and more efficacious drug than other drug products in its class; and/or

g. There were safer alternatives that did not carry the same risks and dangers that Defendants' the Drugs had.

130. The Drugs administered to Plaintiff was defective at the time it was distributed by the Defendants or left their control.

131. The foreseeable risks associated with the design or formulation of the Drugs include, but are not limited to, the fact that the design or formulation of the Drugs is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

132. The defective and unreasonably dangerous design and

marketing of the Drugs was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case.

133. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of the Drugs, Plaintiff suffered personal injuries, economic and non-economic damages, including pain and suffering.

134. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT III

NEGLIGENCE

135. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

136. Defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of the Drugs into the stream of commerce, including a duty to ensure that the products did not cause users to suffer from unreasonable, dangerous side effects.

137. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of the Drugs into interstate commerce in that Defendants knew or should have known that the Drugs created a high risk of unreasonable, dangerous side effects, including causing and increasing the risk of developing pancreatic cancer.

138. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of the Drugs.

139. Despite the fact that Defendants knew or should have known that the Drugs caused unreasonable, dangerous side effects, Defendants continued to market the Drugs to consumers including Decedent.

140. Defendants knew or should have known that consumers such as Decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

141. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted with a conscious disregard of the safety of Decedent as alleged previously.

142. As a proximate and legal result of Defendants' negligence, Plaintiff and Decedent were caused to suffer the herein described injuries and damages.

COUNT IV

BREACH OF IMPLIED WARRANTY

143. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

144. At all times mentioned in this Complaint, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold the Drugs, and prior to the time they was prescribed to Decedent, Defendants impliedly warranted to Decedent, and Decedent's physicians and healthcare providers, that the Drugs were of merchantable quality and safe for the use for which they were intended.

145. Decedent and Decedent's physicians and healthcare providers relied on the skill and judgment of the Defendants in using and prescribing the Drugs.

146. The products were unsafe for their intended use, and they were not of merchantable quality, as warranted by Defendants, in that the Drugs

had very dangerous propensities when put to their intended use and would cause severe injury (or death) to the user. The Drugs were unaccompanied by adequate warnings of their dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

147. As a proximate and legal result of the defective and unreasonably dangerous condition of the Drugs manufactured and supplied by Defendants, Decedent was caused to suffer the herein described injuries and damages.

148. After Plaintiff was made aware or otherwise cam to believe that the injuries discussed herein were a result of the Drugs, notice was duly given to Defendants of the breach of said warranty.

COUNT V

BREACH OF EXPRESS WARRANTY

149. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

150. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the Drugs was expressly warranted to be safe for use by Decedent, and other members of the general public.

151. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Drugs were to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. The Drugs were unaccompanied by adequate warnings of their dangerous propensities that were either known or knowable at the time of distribution.

152. Decedent and Decedent's physicians reasonably relied upon the skill and judgment of Defendants, and upon said express warranty, in using

the Drugs. The warranty and representations were untrue in that the products were unsafe and, therefore, unsuited for the use for which they was intended. The Drugs could and did thereby cause Decedent to suffer the herein described injuries and damages.

153. As soon as the true nature of the products and the fact that the warranty and representations were false were ascertained, Defendants were notified of the breach of said warranty.

COUNT VI

PUNITIVE DAMAGES

154. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

155. Although Defendants knew or recklessly disregarded the fact that the Drugs cause debilitating and potentially lethal side effects, Defendants continued to market the Drugs to consumers, including Decedent, without disclosing these side effects when there were safer alternative methods for treating type 2 diabetes.

156. Defendants knew of the Drugs' defective nature, as set forth herein, but continued to design, manufacture, market, and sell them so as to maximize sales and profits at the expense of the health and safety of the public, including Decedent, in conscious and/or negligent disregard of the foreseeable harm caused by the Drugs.

157. Defendants intentionally concealed or recklessly failed to disclose to the public, including Decedent, the potentially life-threatening side effects of the Drugs to ensure their continued and increased sales. Defendants failed to provide warnings that would have dissuaded physicians from prescribing the Drugs and consumers from purchasing and consuming the Drugs, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or

purchasing and consuming the Drugs.

158. The aforementioned conduct of Defendants was willful and wanton and was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT VII

WRONGFUL DEATH

159. Plaintiff hereby incorporates by reference all paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

160. Plaintiff is the spouse and Successor-in-Interest to the Decedent, who used Defendants' Drugs and was injured and died as a result. Said Decedent was prescribed, supplied with, received, took, used and consumed said Drugs as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants.

161. The injuries and damages the Plaintiff and Decedent were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants.

162. As a result of the conduct of Defendants and the use of Defendants' Drugs, the Decedent suffered catastrophic and ultimately fatal injuries.

163. As a result of the death of the Decedent, Plaintiff was deprived of love, companionship, comfort, affection, society, solace and or moral support of the Decedent.

164. Plaintiff is entitled to recover economic and non-economics

damages against all Defendants for wrongful death directly and legally caused by the defects in defendants' Drugs and the negligent conduct, acts, errors, omissions and intentional and negligent misrepresentations of Defendants, and each of them.

165. The Successor-in-Interest of the Decedent's estate further pleads all wrongful death damages allowed by statute and law in the state or states in which the causes of action accrued.

COUNT IIX

SURVIVAL ACTION

166. Plaintiff hereby incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

167. As a direct and proximate result of the Defendants' conduct, and failure to comply with applicable standards, as outlined above, the Decedent suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to the Decedent's death.

168. The Successor-in-Interest of the Decedent's estate brings this claim on behalf of the Decedent's estate and the Decedent's beneficiaries for damages.

169. The Successor-in-Interest of the Decedent's estate further pleads all survival damages allowed by statute and law in the state or states in which the causes of action accrued.

PRAYER FOR RELIEF FOR SURVIVAL AND WRONGFUL DEATH

WHEREFORE, Plaintiff prays for relief as follows:

1. Actual damages as alleged, jointly and/or severally against

Defendants, in excess of $75,000.00;

2. Economic damages, including, as applicable, wage loss and loss of earning capacity, in an amount to be determined at trial of this action;
3. Medical expenses, including for past and future treatment, in an amount to be determined at trial of this action;
4. Non-economic damages, including pain and suffering;
5. All wrongful death and/or survival damages;
6. Burial and funeral expenses;
7. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of $75,000.00;
8. All pre- and post-judgment interest at the highest legal rate available under relevant law;
9. Attorneys' fees, expenses, and costs of this action; and
10. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

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Dated: September 10, 2015

Respectfully submitted,
WATTS GUERRA LLP

/s/ Ryan L. Thompson
Ryan L. Thompson
CA Bar No. 296841
5726 Hausman Rd., Suite 119
San Antonio, Texas 78249
Office: 210.448.0500
Fax: 210.448.0501
rlt-bulk@wattsguerra.com

Ramon Rossi Lopez, Bar No. 86361
Matthew Ramon Lopez, Bar No. 263134
LOPEZ McHUGH LLP
100 Bayview Circle
Suite 5600, North Tower
Newport Beach, CA 92660
Telephone: (949) 737-1501
Facsimile: (949) 737-1504
rlopez@lopezmchugh.com
mlopez@lopezmchugh.com

Attorneys for Plaintiff